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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD. Plaintiff, v. SILARX PHARMACEUTICALS, INC. Defendant.	Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendant Silarx Pharmaceuticals, Inc. ("Silarx"), alleges as follows:

THE PARTIES

1. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan. Otsuka is engaged in the research, development, manufacture and sale of pharmaceutical products.

2. Upon information and belief, Silarx is a corporation organized under the laws of the State of New York, and its principal place of business is located at 19 West Street, Spring Valley, NY 10977.

NATURE OF THE ACTION

3. This is an action for infringement of United States Patent Number 6,977,257 ("the '257 patent"), arising under the United States patent laws, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. § 271 and 281. This action relates to Silarx's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j) seeking U.S. Food and Drug Administration ("FDA") approval to market a generic pharmaceutical product ("Silarx's generic product").

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

5. Upon information and belief, this Court has jurisdiction over Silarx because at a minimum it (1) is registered to do business in this judicial district, (2) retains a registered agent in this judicial district, (3) conducts business within this judicial district, (4) directly, or indirectly, manufactures, markets, sells, and distributes generic drugs throughout the United States and in this judicial district, (5) purposefully has conducted and continues to conduct business in this judicial district, and (6) this judicial district is a likely destination of its generic products.

6. Otsuka received a letter from Silarx dated August 1, 2012, purporting to include an Offer of Confidential Access for ANDA No. 20-4171. Upon information and belief, this Court additionally has jurisdiction over Silarx because it has availed itself of the rights and benefits of this judicial district, having stated in its Offer of Confidential Access that "[t]his Offer of Confidential Access shall be governed by the laws of the State of New Jersey."

7. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and 1400(b).

FIRST COUNT FOR PATENT INFRINGEMENT

8. The U.S. Patent and Trademark Office ("PTO") issued the '257 patent on December 20, 2005, entitled "Aripiprazole Oral Solution." A copy of the '257 patent is attached as Exhibit A.

9. The '257 patent is assigned to Otsuka. Otsuka is the owner of the '257 patent as recorded by the PTO at Reel 017586, Frame 0036.

10. The '257 patent expires on October 24, 2022 (including pediatric exclusivity).

11. The '257 patent claims, *inter alia,* oral aripiprazole solutions.

12. Otsuka is the holder of NDA No. 21-713 for aripiprazole oral solution, which the FDA approved on December 10, 2004. The Orange Book lists the '257 patent for NDA No. 21-713.

13. Otsuka manufactures and sells aripiprazole oral solution in the United States under the trademark Abilify®.

14. Upon information and belief, Silarx filed with the FDA ANDA No. 20-4171, under Section 505(j) of the Act, 21 U.S.C. § 355(j).

15. Upon information and belief, Silarx's ANDA No. 20-4171 seeks FDA approval to sell in the United States Silarx's generic product.

16. Otsuka received a letter from Silarx dated August 1, 2012, purporting to include a Notice of Certification for ANDA No. 20-4171 ("Silarx's 20-4171 letter") under 21 U.S.C. § 355(j)(2)(a)(vii)(IV), 21 C.F.R. § 314.95(a)(12)(i)(A)(4) and 21 C.F.R. § 314.95(c).

17. Silarx's 20-4171 letter alleges that the active ingredient in Silarx's generic product for which it seeks approval is aripiprazole.

18. Upon information and belief, Silarx's generic product will, if approved and marketed, infringe at least one claim of the '257 patent.

19. Under 35 U.S.C. § 271(e)(2)(A), Silarx has infringed at least one claim of the '257 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-4171 seeking approval for the commercial marketing of Silarx's generic product before the expiration date of the '257 patent.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against the Defendant on the patent infringement claims set forth above and respectfully requests that this Court:

1) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Silarx has infringed at least one claim of the '257 patent through Silarx's submission of ANDA No. 20-4171 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Silarx's generic product before the expiration of the '257 patent;

2) order that the effective date of any approval by the FDA of Silarx's generic product be a date that is not earlier than the expiration of the '257 patent, or such later date as the Court may determine;

3) enjoin Silarx from the commercial manufacture, use, import, offer for sale and/or sale of Silarx's generic product until the expiration of the '257 patent, or such later date as the Court may determine;

4) enjoin Silarx and all persons acting in concert with Silarx, from seeking, obtaining or maintaining approval of Silarx's ANDA No. 20-4171 until the expiration of the '257 patent;

5) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Otsuka costs, expenses and disbursements in this action, including reasonable attorney fees; and

6) award Otsuka such further and additional relief as this Court deems just and proper.

Respectfully submitted,

/s/ John F. Brenner

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